

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Claim 1. (Previously Presented) A stable pharmaceutical formulation for inhalation through nebulisation consisting of a solution of a steroid in which:

- a) the steroid concentration ranges from 0.01 % to 0.1 %;
- b) the liquid component of the solution is a mixture of water and propylene glycol in a ratio ranging from 60:40 to 30:70 v/v; and
- c) the pH ranges from 3.5 to 5.0, the pH of the formulation having been adjusted by the addition of a concentrated strong acid to the solution; wherein the percentage of nebulised active ingredient particles with MAD below 6 μm is higher than 70 % and the nebulisation efficiency is higher than 20 %.

Claim 2. (Previously Presented) The formulation according to claim 1, wherein the liquid component of the solution consists of water and propylene glycol in a 50:50 v/v ratio.

Claim 3. (Previously Presented) The formulation according to claim 1, wherein the pH of the solution ranges from 4.0 to 4.5 and has been adjusted by the addition of HCl to the solution.

Claim 4. (Previously Presented) The formulation according to claim 1, wherein the steroid is in the form of an acetal or is in the form of an acetonide .

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Claim 5. (Currently Amended) The formulation according to claim 4, wherein the steroid ~~acetal is in the form of an acetal of~~ is budesonide ~~or the epimers thereof.~~

Claim 6. (Currently Amended) The formulation according to claim 4, wherein the steroid ~~in the form of acetone is an acetone of~~ is flunisolide.

Claim 7. (Previously Presented) The formulation according to claim 5, wherein the concentration of budesonide in the solution ranges from 0.025 to 0.05 %.

Claim 8. (Previously Presented) The formulation according to claim 6, wherein the concentration of flunisolide in the solution is 0.1 %.

Claim 9. (Previously Presented) The formulation according to claim 1, wherein the osmolarity of the solution is not more than 7500 mOsm/l.

Claims 10 and 11. (Canceled)

Claim 12. (Previously Presented) The formulation according to claim 9, wherein the osmolarity of the solution is not more than 7000 mOsm/l.

Claim 13. (Currently Amended) A process for the preparation of pharmaceutical formulations according to claim 1, which comprises:

- a) preparing a propylene glycol solution of a steroid at a temperature of 40 to 50° C;
- b) cooling the solution, by and then diluting the solution with water;

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c) adjusting the pH of the solution by the addition of a concentrated, strong acid thereto; and

d) filtering the solution and distributing the solution to containers for the treatment of individuals by nebulisation.

Claim 14. (Previously Presented) The process according to claim 13, wherein the pH of the solution is adjusted to a range of 3.5 to 5.0.

Claim 15. (Previously Presented) The process according to claim 13, wherein the propylene glycol solution of the steroid is diluted with water to a water and propylene glycol ratio ranging from 60:40 to 30:70 v/v.

Claim 16. (Previously Presented) The process according to claim 13, wherein the strong acid is hydrochloric acid.

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